

May 24, 2011

Montana Health Care Programs Notice

Mid-Level Practitioner, Physician, Public Health Clinic

Effective June 1, 2011

17 Alpha-Hydroxyprogesterone Caproate (17-AHP) and Makena

Montana Medicaid encourages the use of clinically appropriate and cost effective medications in treatment regimens. The use of the compound 17 Alpha-Hydroxyprogesterone Caproate (17-AHP) has and continues to be a covered physician administered drug. In February 2011, Makena™, also a hydroxyprogesterone caproate, received FDA approval to be used to reduce the risk of preterm birth in women who are pregnant with a single baby and who have delivered a preterm baby in the past.

Montana Medicaid encourages providers to rely on their prior success with compounded 17-AHP when making treatment decisions for their patients. The compounded 17-AHP is not an FDA-recognized A-rated substitute for prescriptions written for Makena; therefore, 17-AHP cannot be legally substituted at the pharmacy level for a prescription written for Makena. Physicians must order 17-AHP from a specialty compounding pharmacy.

The FDA announced it does not intend to take enforcement action against pharmacies that compound hydroxyprogesterone caproate based on a valid prescription for an individually identified patient unless the compounded products are unsafe, of substandard quality, or are not being compounded in accordance with appropriate standards for compounding sterile products. See <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm249025.htm>.

Due to prior success with 17-AHP coupled with the narrow indications of Makena, Montana Medicaid will require prior approval for the use of Makena over the compound. A letter requesting prior approval for the use of Makena should be sent to Physician-Related Services, DPHHS, P.O. Box 202951, Helena, MT 59620-2951.

The prescribing physician will be required to demonstrate the medical necessity of the manufactured product over the compounded 17-AHP product to obtain prior approval. The DPHHS approval letter must be attached to any claim submitted for Makena.

See the [provider notice](#) dated November 17, 2010, for instructions for billing 17-AHP.

Contact Information

For claims questions or additional information, contact Provider Relations:

Provider Relations toll-free in- and out-of-state: 1-800-624-3958

Helena: (406) 442-1837

E-mail: MTPRHelpdesk@ACS-inc.com

Visit the Provider Information website:

<http://medicaidprovider.hhs.mt.gov>